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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/522,153

10/31/2005

Teruo Kirikae

Q85911

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65565 7590 03/13/2008
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EXAMINER

KIM, YUNSOO

ART UNIT

PAPER NUMBER

1644

MAIL DATE

DELIVERY MODE

03/13/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/522,153 | KIRIKAE ET AL. | |
| | Examiner | Art Unit | |
| | YUNSOO KIM | 1644 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 1-6, 20-24 and 30-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-19 and 25-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/24/05</u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Claims 1-32 are pending.

Applicant's election without traverse of Group II, claims 7-19 and 25-29, in the reply filed on 1/10/08 is acknowledged.

Claims 1-6, 20-24 and 30-32 are withdrawn from further consideration by the examiner 37 CFR. 1.142(b) as being drawn to a nonelected invention.

Accordingly, claim 7-19 and 25-29 are under consideration.

2. Applicants' IDS filed on 1/24/05 has been considered.

However, the international search report dated 9/2/03 has been considered but crossed out as being inappropriate to be printed on the front page of an issued patent. Moreover, Hirata et al. 2001 reference has not been considered because the reference is in Japanese. Applicant is required to provide a translation.

3. Sequence compliance: The instant application appears to be in sequence compliance for patent applications containing amino acid sequence disclosures.

4. Applicant's claim for foreign priority under 35. U.S.C. 119(a)-(d) is acknowledged.

5. Claims 7-18 and 25-27 are objected to because of the following informalities: The quotation marks are noted in claims 7-18 and 25-27. The quotation marks are being used to set off a portion of text for variety of purposes and the marks do not provide clear purposes. Appropriate correction is required.

Moreover, claims 7-19 and 25-27 are objected to because claims 7 and 25 are being depended on a non-elected claim and should be written as an independent claim.

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Furthermore, claims 7, 8, 10-12, 15, 16, 26 and 27 are objected to because of the following informalities: Applicant is required to replace the phrase "represented by" in claims 7, 8, 10-12, 15, 16, 26 and 27 to "of" for greater clarity of the claims.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 7-19 and 25-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ailsa Campbell (Monoclonal Antibody and Immunosensor Technology, Elsevier, p. 51-96) and Ailsa Campbell (Monoclonal Antibody Technology, 1984, p. 1-31, of record) in view of Swierko et al (J. Med. Microbiol. vol. 49, p. 127-138, 2000, IDS reference).

Campbell teaches immunoassay system using antigen-antibody complex. Campbell teaches attachment of antigen on a solid support (p.63-64), use of labeled antibody and secondary antibody (p.71-75), solid phase assays (p. 82-88) and ELISA for any bacterial or cellular antigens (p. 91-96).

Campbell (Monoclonal Antibody Technology, 1984, p. 1-31) teaches that monoclonal antibodies are useful for therapeutic, diagnostic, preparative and basic research purposes (p. 1-20) and it is customary for any group working on a protein to make monoclonal antibodies to it (p. 29).

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Campbell does not teach use of SEQ ID NO:1 and the antibody binds to SEQ ID NO:1.

However, Swierko et al. teach that the claimed SEQ ID NO:1 is derived from human CAP18 and this 27 amino acid segment (CAP18₁₀₉₋₁₃₅) is clinically important as it is LPS neutralizing domain and antimicrobial domain (p. 128, under reagent). Swierko et al. further teach that the bacteria *Proteus* cause pneumonia and the LPS from *Proteus* strain are endotoxic (abstract, introduction). Moreover, treatment of *proteus* LPS with CAP18₁₀₉₋₁₃₅ weakens the endotoxicity of LPS and CAP18₁₀₉₋₁₃₅ binds LPS (p. 136-137, discussion).

It would have been obvious to one of the ordinary skill in the art at the time the invention was made to substitute general antibody-antigen interaction with the antibody that binds to SEQ ID NO:1 and the protein comprises SEQ ID NO:1 as taught by Swierko et al. as an antibody and antigen of interest into the solid phase and ELISA immunoassay techniques taught by Campbell.

One of the ordinary skill in the art would have been motivated to do so because using antigen and antibody interaction in immunoassay provides a diagnostic tool in LPS/CAP18 in bacterial infection and the immunoassay system is well known in the art. Moreover, generating monoclonal antibody to a protein of interest provides powerful immunochemical tools useful for therapeutic, diagnostic and preparative purposes based on their specificity for binding, their homogeneity and their ability to be produced in unlimited quantities (Campbell, *Monoclonal Antibody Technology*, 1984, p. 1-31).

From the teachings of references, it would have been obvious to one of the ordinary skill in art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary skill in the art at the time of invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

8. No claims are allowable.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on M-F, 9-5.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Yunsoo Kim

Patent Examiner

Technology Center 1600

February 26, 2008

/Eileen B. O'Hara/

Supervisory Patent Examiner, Art Unit 1644